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STATE PASS TO USTR

E.O. 12958: DECL: 02/12/2016
TAGS: ETRD KIPR KTIA BEXP PGOV ECON EIND JO
SUBJECT: JORDAN FOCUSING ON PHARMACEUTICAL IPR ISSUES

REF: A. GROVES/SAUMS (USTR) - LAWLESS EMAIL OF 02/11/06
¶B. 05 AMMAN 9748

Classified By: CDA DANIEL RUBINSTEIN FOR REASONS 1.4 (B, D)

¶1. (C) SUMMARY: Charge delivered ref (A) points from the Office of the U.S. Trade Representative (USTR) to Jordan Food and Drug Administration (JFDA) Director General Salah Mawajdeh February 12, noting they answered ref (B) request for the USG assessment of pharmaceutical IPR protection in Jordan. Charge emphasized the U.S. takes seriously the issue of IPR protection; in the context of a positive and cooperative trading relationship, there was an expectation the Government of Jordan (GoJ) could take additional measures in the very near future. DG Mawajdeh said he had met with PhRMA companies on IPR issues in what he termed a "positive" exchange (with more meetings scheduled), and wondered why there still appeared to be a "gap" in communications. Charge noted that USTR,s views had been presented to Trade Minister Zu'bi during his recent visit to Washington and that these views still held, inasmuch as they reflected the "snapshot" reality on the ground today. He encouraged the JFDA to pursue an outcomes-based approach. If the JFDA were contemplating taking actions to address IPR concerns, this should be communicated in the GoJ's Special 301 Review submission. NOTE: Later the same day, DG Mawajdeh met with PhRMA representatives, who reportedly told him that they had little choice but to recommend Jordan for the Special 301 Watch List unless the GoJ finally put in writing its commitments, with a timetable for progress by late March. END NOTE. Post believes that GoJ authorities are now more focused on the pharmaceutical IPR issue, although Ministry of Industry and Trade contacts suggest that these highly technical issues could take time to resolve. END SUMMARY.

No Time Like Now

¶2. (C) Charge reviewed the Special 301 process with DG Mawajdeh, noting that it would generally rely on a snapshot of Jordan's actions up through April, 2006. He highlighted data exclusivity, new uses, and marketing approvals among the technical IPR issues unresolved after the December 2004 deadline for compliance, and still of concern to the USG. It appeared, he said, that Jordan is doing less than all which it is required to by its FTA obligations. He urged the JFDA to communicate in a February 13 Special 301 Review country submission what actions it planned to take to address the IPR concerns in play, and noted that the USTR would be prepared to discuss these issues directly with the JFDA and to provide technical assistance if required. If the GoJ planned to implement additional measures, there was no time like now.

¶3. (C) Mawajdeh said the JFDA participated in a "gap analysis" on the FTA and IPR obligations prepared by the USAID Achievements in Market Friendly Initiatives and Results

(AMIR) program that was published January 26. Mawajdeh also met with PhRMA company representatives on February 8 to decide what to do about the IPR issues. They agreed to form four working groups on IPR, regulatory, and pricing issues which would make recommendations to be reviewed by the JFDA Higher Council by the end of March, he said. He did not see all of the PhRMA points as issues of concern, or in other instances there was no practical solution, but the JFDA would work on them. Given the new, positive platform for discussion and review of the issues, he expressed surprise that there still appeared to be some industry discontent.

No Regulations, Yet

¶4. (C) Charge reiterated the importance of the USTR analysis, independent of any other views. The USTR points reflect our understanding of the actual picture on the ground today. DG Mawajdeh expressed the view that it was enough for JFDA to have committed to discuss the idea of making explicit the protections being offered "new uses" and related implications (a point in the ref (A) USTR paper) in a committee. When asked, he acknowledged that these FTA commitments were not presently contained in any official documents such as regulations or instructions.

¶5. (C) Charge stressed that the USG wanted to have a fair process of review, which included an assessment of Jordan's IPR actions that was accurate, fair and complete. There may be definitional issues or matters of tone or emphasis that could best be worked out through continued and timely communication. Mawajdeh acknowledged the Embassy offer to convey new developments, and took on board the need to arrange direct meetings with a USG technical group, noting digital video conferences might be possible.

¶6. (C) NOTE: Later on February 12, five representatives of PhRMA companies called on DG Mawajdeh, according to a conference call read-out to Econoff. Their mission was to convey the group's consensus decision on February 11 to recommend Jordan for Watch List status. They said that Mawajdeh expressed dismay that their actions since the February 8 JFDA-PhRMA meeting had not been consistent with the "spirit of cooperation" he thought they achieved. Privately, PhRMA members revealed to Econoff the decision was driven by a sense of frustration at various verbal promises made without concrete action, and the sense that the JFDA Higher Council was being brought too deeply into the implementation of government commitments made by bilateral agreement in 2001. One PhRMA member said that Mawajdeh was now "on the run" and would be more focused on achieving results.

¶7. (C) COMMENT: Notwithstanding continual Embassy efforts since late 2003 to encourage JFDA action on the pharma IPR front, JFDA historically has seen its main function as acting on each drug registration case from a drug approval stance, with safety and efficacy for the patient being the primary concerns. With the transmission of USG viewpoints in Ref (A) and the most recent, candid interaction between JFDA and industry representatives, it would appear that JFDA now understands there is a pressing need to reach closure on IPR issues. However, while the Ministry of Industry and Trade is expecting a brief summary from JFDA to insert into the GoJ Special 301 Review submission on February 13, Trade Ministry contacts warn that these technical issues are not easily resolved. We take that as a hint that Jordan's increasingly powerful generic pharmaceutical industry will be in the background, pressing for any advantage it can secure in pharmaceutical market access issues.
Rubinstein